SUMMARY OF THE
TNI CHEMISTRY EXPERT COMMITTEE MEETING

OCTOBER 3, 2013

The Committee held a conference call on Thursday, October 3, 2013, at 2:00 pm EDT.

1 – Roll call

Richard Burrows, Test America (Lab)	Present
Francoise Chauvin, NYC DEP (Lab)	Present
Brooke Connor, USGS (Other)	Absent
Dan Dickinson, NYSDOH (Accreditation Body)	Present
Mandi Edwards, Envirochem (Lab)	Present
Tim Fitzpatrick, Florida DEP (Lab)	Present
Andrew Friedrich, Chevron (Lab)	Absent
Nancy Grams, Advanced Earth Technologists, Inc. (Other)	Absent
Anand Mudambi, USEPA (Other)	Absent
John Phillips, Ford Motor Co., (Other)	Present
Scott Siders, IL DEP (AB)	Present
Gary Ward, OR DPH (AB)	Present
Ken Jackson, Program Administrator	Present

Associate Committee members present: Jane Arrington; Arthur Denny; Shu Liu; Diana Shannon

2 – Previous Minutes

It was moved by John and seconded by Francoise to approve the minutes of September 5, 2013. All were in favor. It was moved by Tim and seconded by Mandi to approve the minutes of September 19, 2013. All were in favor.

3 – Calibration Voting Draft Standard

Tim had e-mailed proposed edits to Section 1.7.1.1 e. He had added a proposed footnote reading:

"[b]*Fewer standards and degrees of freedom may be used only if equipment firmware or software cannot accommodate the specified number of standards. Documentation from the equipment manufacturer detailing that limitation must be maintained by the laboratory.*"

He explained the rationale was if a piece of software or firmware required a linear fit with only 3 points rather than the normally required 4 points, it would be allowed. It was

pointed out that supporting documentation from the equipment manufacturer may not always be available (e.g., with an old piece of equipment), and after some discussion it was agreed to delete from the last sentence "*from the equipment manufacturer*"; i.e., the laboratory must just have documented auditable proof of this limitation.

As a consequence of discussion on the previous call, Tim had also sent in the following proposed language for 1.7.2 e, saying what must be done in order to continue after a failed CCV.

"Criteria for the acceptance of a continuing instrument calibration verification shall be established. If the continuing instrument calibration verification results obtained are outside the established acceptance criteria, the following steps shall be taken:

i. if an obvious cause for the calibration verification failure is identified that impacts only the calibration verification sample (e.g. a missed autosampler injection), then analysis may proceed if a second calibration verification sample is analyzed immediately and the result is within acceptance criteria. Samples analyzed previously shall be considered valid if bracketed by a passing calibration verification sample (refer to 1.7.2(d)). The cause for the failure of the first calibration verification result shall be documented;

ii. if the cause for the calibration verification failure is not obvious and/or has the potential to have impacted other samples, then corrective action shall be performed and documented. Prior to analyzing samples, the laboratory shall demonstrate acceptable performance after corrective action with calibration verification or a new initial calibration shall be performed; Samples analyzed prior to the calibration verification failure shall be reanalyzed or the results qualified if calibration verification bracketing is required (refer to 1.7.2(d));

iii. If samples are analyzed using a system on which the calibration has not been verified, the results shall be qualified. Data associated with an unacceptable calibration verification may be fully useable under the following special conditions:

> *I. when the acceptance criteria for the continuing calibration verification are exceeded high (i.e., high bias) and there are associated samples that are non-detects, then those non-detects may be reported. Otherwise the samples affected by the unacceptable calibration verification shall be re-analyzed after a new calibration curve has been established, evaluated and accepted; or*
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> *II. when the acceptance criteria for the continuing calibration verification are exceeded low (i.e., low bias), those sample results may be reported if they exceed a maximum regulatory limit/decision level. Otherwise the samples affected by the unacceptable verification shall be re-analyzed after a new calibration curve has been established, evaluated and accepted."*

The Committee agreed to incorporate this language.

Dan had e-mailed the following modifications to 1.7.1.1 d), f), and g) to address voters' comments.

d) "*criteria shall be established by the laboratory for the rejection of any calibration standards analyzed but not used to generate an initial calibration. The reason for the rejection of any calibration standard shall be documented and any data below the lowest or above the highest remaining calibration standard that must be reported shall be identified as estimates and qualified per section 1.7.1.1 g and f. The calibration generated from the remaining calibration standards shall satisfy all the requirements specified for initial calibrations."*

f) "*the lowest calibration standard shall be at or below the lowest concentration for which quantitative data are to be reported without qualification; Any data reported below the lowest calibration standard shall be reported using defined qualifiers and explained in the narrative."*

g) "*the highest calibration standard shall be at or above the highest concentration for which quantitative data are to be reported without qualification; Any data reported above the highest calibration standard shall be reported using defined qualifiers and explained in the narrative."*

In the 2nd sentence of d), Tim suggested saying *"..any data reported below…*". Scott suggested changing "*estimates*" to "*estimated*". He also suggested f) and g) should use similar language to d) ("qualified as estimated"). Dan wondered how all this would appear in a check-list; i.e., which item would be cited if an assessor saw data reported that were outside the calibration range. He added that d) speaks more to having the documentation in-house, while f) and g) might be more appropriate to cite where it was documented but they didn't do it.

Scott was concerned the standard did not make it clear enough when calibration points could be dropped, and this had been raised in several voters' comments. This led to a lengthy discussion. He gave the example of a laboratory running a 5-point linear-fit calibration curve, and needing to drop one calibration concentration. The laboratory would still meet the minimum requirement with only 4 points. However, if the laboratory ran a 4-point curve and dropped one, then it would no longer meet the minimum requirement. He questioned if this was clear in the last sentence of d). John said if you have a multi-analyte standard and you have a valid reason for dropping one or two of the standards, it needs to be clear you must drop the entire standard and not just the analytes in question. Francoise agreed, since an analyst could make a mistake in spiking just one of the calibration standards and that would be a technically valid reason to drop it. Richard felt more language was needed to make it clear that points at the upper or lower levels of the curve could be dropped, since that would just change the calibration range. However, if a point was dropped in the middle of the curve, it might be acceptable if that point was dropped for all the analytes in the mix and if the laboratory can document what was wrong for that level (e.g., a bad injection). It was agreed that re-wording this section

could satisfy at least one of the persuasive comments (e.g., Dorothy Love, Section 1.7.1.1 d)). However, Richard said it could be difficult to document in the standard the multitude of technically valid reasons for dropping a calibration point. Dan agreed to work on the language again, and would also look at reducing the redundancy between d), f) and g). He said he would circulate his revised language before the next call to give everyone an opportunity to comment and offer suggestions.

Francoise had e-mailed a proposed revision to Section 1.7.1. She re-worded it so it would not apply to supporting equipment. A discussion followed on differentiating between support equipment and analytical measurement equipment. Tim suggested if equipment uses the calibration model to derive a concentration it is not support equipment. However, the distinction may not be clear-cut; e.g., TSS uses a balance, which is normally considered to be support equipment. There was a suggestion to list support equipment, but Richard warned that inevitably something would be omitted from the list. It was agreed to modify the first sentence to read "*This module specifies the essential elements that shall define the procedures and documentation for initial calibration with second source verification and continuing calibration verification for methods that use calibration models such as average response factor or linear or quadratic regression, to ensure that the data shall be of known quality for the intended use*." This was followed by the additional sentence: "*Calibration requirements for analytical support equipment are specified in Module 2.*"

Francoise had e-mailed the following re-draft of section 1.7.1.1 k) (iv) in response to a persuasive comment by Steve Arms. " *Sample results within the established linear dynamic range will not require data qualifiers regarding range exceedance. Samples with results above the linear dynamic range must be diluted, or the over-range results qualified as estimated values.*"

She suggested using the term "linear dynamic range", as in EPA 200.7 9.2.2, to clarify the distinction between this linear dynamic range and the range used in the one-point-calibrations.

The committee agreed with this language.

The only comments remaining to be discussed were general comments where specific sections of the standard were not identified, and those submitted as attachments. They would require going section-by-section through the standard. To facilitate this, Richard said prior to the next call he would distribute a revised standard incorporating all the changes agreed to date.

The next call was scheduled for October 17, 2:00 – 3:30 pm Eastern Time.

5 – Adjournment

The call was adjourned at 3:30 pm EDT